DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 26 2010

Re: Acyclovir and Hydrocortisone Cream
Docket No. FDA-2010-E-0330

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. RE 39,264 filed by Medivir AB, under 35 U.S.C. § 156. The human drug product claimed by the patent is Acyclovir and Hydrocortisone Cream (acyclovir and hydrocortisone), which was assigned new drug application (NDA) No. 22-436.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that Acyclovir and Hydrocortisone Cream does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredients in Acyclovir and Hydrocortisone Cream have been previously approved as individual components for commercial marketing or use in many other new drug applications, including GlaxoSmithKline's Acyclovir ointment, oral suspension, tablets, capsules and injection; Pfizer's Hydrocortisone ointment, tablets and injection; Ani Pharms' Cortenema rectal solution, and others.

The NDA was approved on July 31, 2009, which makes the submission of the patent term extension application on September 28, 2009, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy

Center for Drug Evaluation and Research

cc: Susan W. Gorman
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